EXHIBIT E

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Q2Administrators℠
A CMS Contracted Qualified Independent Contractor (QIC)

May 07, 2019

J. Olsen

RE: Medicare Administrative Law Judge Appeal Number 1-8237389961
Appellant: J. Olsen
Beneficiary: J. Olsen

Dear Appellant:

This letter is to inform you that Medicare's Administrative Qualified Independent Contractor (AdQIC) is referring the Administrative Law Judge's decision dated March 14, 2019, and the related claim file(s) to the Medicare Appeals Council for possible review on the Council's own motion.

Among our responsibilities as the AdQIC is reviewing Administrative Law Judge (ALJ) decisions and dismissals. We may refer an ALJ decision or dismissal to the Council if, in our view, the decision or dismissal contains an error of law material to the outcome of the claim or presents a broad policy or procedural issue that may affect the public interest. In the event the Centers for Medicare and Medicaid Services or its contractor participated in your Medicare appeal at the ALJ level, we may also refer the case if we believe the ALJ's decision or dismissal is not supported by the preponderance of evidence in the record or the ALJ abused his or her discretion. In deciding whether to accept own motion review, the Council will limit its consideration of the ALJ's action to the exceptions raised in our referral.

You are not required to take any further action. However, you may file exceptions to our referral by submitting written comments to the Council within twenty calendar days of the referral notice. Submit written comments to the following address:

Department of Health and Human Services
Departmental Appeals Board, MS 6127
Medicare Appeals Council
Cohen Building, Room G-644
330 Independence Avenue, S.W.
Washington, D.C. 20201

You must also send a copy to the AdQIC at the address below and all other parties to the ALJ's decision who received a copy of the hearing decision or notice of dismissal. For additional information regarding Medicare Appeals Council reviews, see section 405.1110 of Title 42 of the Code of Federal Regulations. Please find a copy of our referral attached for your review.

Sincerely,

Q2Administrators, LLC
Administrative Qualified Independent Contractor

CC: Medicare Appeals Council
Chief Administrative Law Judge Griswold (referral memorandum only)
Minimed Distribution Corp., Attn: Legal Dept., 18000 Devonshire Street, Northridge, CA 91325
Karen Olsen, [redacted]

CMS
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CMS Referral for Own Motion Review by DAB/MAC

Appellant at ALJ Level	ALJ Appeal Number
J. Olsen	*1-8237389961*
Beneficiary (if not the Appellant) ☐List attached	ALJ Decision Date
J. Olsen	*March 14, 2019*
Health Insurance Claim Number (HICN) [redacted]	Specific Item(s) or Service(s) *A9276 (Disposable CGM sensor); A9277 (External transmitter); A4452 (Waterproof tape)*
Provider, Practitioner or Supplier *MiniMed Distribution Corp.*	☐ **Part A** ☒ **Part B**

Basis for referral

Any Case	**CMS as a Participant**
☒ Error of law material to the outcome of the claim	☐ Decision not supported by the preponderance of evidence
☐ Broad policy or procedural issue of public interest	☐ Abuse of discretion

Rationale for Referral:

On March 14, 2018; April 18, 2018; and June 5, 2018, Minimed Distribution Corp. (Supplier), a supplier of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), furnished supplies for use with a continuous blood glucose monitor (CGM) to a Medicare beneficiary (Appellant). Claims were submitted to Medicare for the supplies, which were described using the Healthcare Common Procedural Coding System (HCPCS)[1] code A9276 (Sensor; invasive (e.g., subcutaneous), disposable, for use with interstitial CGM system, one unit = 1 day supply); A9277 (Transmitter; external, for use with interstitial CGM system); and A4452 (Tape, waterproof). The DME Medicare contractors denied the claims, in part, upon findings that the items were not covered by Medicare.

Appellant requested a hearing before an Administrative Law Judge (ALJ). The ALJ held a telephonic hearing and subsequently issued a decision that was fully favorable for Appellant. The ALJ noted that the QIC had denied coverage on the basis that the record did not contain an order for the items at issue and then only discussed that issue in his decision. The ALJ found that the record contained a signed and dated order and thus Medicare allowed coverage and payment for the items at issue under § 1862(a)(1)(A) of the Social Security Act (the Act).

[1] The Centers for Medicare and Medicaid Services (CMS) developed HCPCS to establish a standardized coding system for processing, screening and paying Medicare claims. See *HCPCS – General Information*, online at https://www.cms.gov/medicare/coding/medhcpcsgeninfo/index.html (visited April 19, 2019).

The ALJ decision and case file(s) are enclosed.

Signature	Date of Referral
Sarah W. Garrod	*May 7, 2019*
Sarah W. Garrod, JD	

Contractor effectuation will be delayed until the Medicare Appeals Council issues its decision.

The ALJ erred as a matter of law by not addressing the issue of non-coverage of the items at issue. Generally, "[t]he issues before the ALJ . . . include all the issues for the claims or appealed matter . . . that were brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor." 42 CFR § 405.1032(a). The DME Medicare Administrative Contractor's (MAC) initial denial and redetermination decision addressed the issue of Medicare non-coverage of the items. Specifically, the MAC's redetermination for the sensor and transmitter at issue denied the items, explaining, "CGM devices covered by Medicare under the DME benefit are defined in CMS Ruling 1682R as therapeutic CGM. CGM devices that do not meet the definition of a therapeutic CGM as defined in CMS Ruling 1682R will be denied as non-covered (no benefit)." Exh 1 at 30. However, the ALJ did not address this issue.

The ALJ also erred as a matter of law by not applying the CMS ruling and Medicare regulatory provisions regarding DME coverage. Regulations and CMS rulings are binding authority for an ALJ. 42 CFR § 405.1063. Medicare sets forth the requirements for an item to be considered DME for the purposes of Part B Medicare payment. See 42 CFR § 414.202. CMS Ruling 1682-R (the Ruling),[2] effective January 12, 2017, explained that a CGM system may be eligible for Medicare coverage under the DME benefit when the system qualifies as a therapeutic CGM that meets the definition of a DME. The Ruling defined a therapeutic CGM system as one that was "designed and approved to replace a blood glucose monitor currently classified as DME under the Medicare program" and emphasized that the US Food and Drug Administration (FDA) must have approved the CGM "for use in place of a blood glucose monitor for making diabetes treatment decisions." Although the Ruling noted that the glucose sensors in a CGM system are not durable, it allows payment for "replacement of essential accessories" used with *therapeutic* CGMs, including sensors. The ALJ's analysis did not evaluate whether the FDA had approved the CGM system at issue "to replace a blood glucose monitor," qualifying it as therapeutic under the Ruling, and did not analyze whether the item at issue met the definition of a DME. This error is material to the outcome of the claim because it led to an order for Medicare to cover under the DME benefit accessories used with an item that did not satisfy the definition of DME.

Background:

Appellant was a 40-year-old male on most of the dates of service who was diagnosed with Type I insulin-dependent diabetes. See Exh 2 at 45. The beneficiary's health issues included gastroparesis, neuropathy, with recent history of kidney transplant and pancreas failure. Id. Appellant's physician described his diabetes control as "currently managing his blood sugar with a Medtronic insulin pump. He is required to adjust his does multiple times per day based on carbohydrate intake, blood sugar levels and activity," and that "[h]e has hypoglycemia unawareness and would benefit from the newer technology provided by the Medtronic 670 G model which uses a continuous glucose sensor to help reduce blood sugar excursions and hypoglycemia and associated complications." Id. On March 14, 2018; April 18, 2019; and June

[2] This ruling is available online at https://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/Downloads/CMS1682R.pdf (visited April 19, 2019).

5, 2018, Supplier furnished 180 units of sensors (A9276); 1 transmitter (A9277); and ten units of waterproof tape (A4452). The DME MAC denied the claim, stating that "Medicare does not pay for this item or service." Id at 39, 40, 41, 42; see id at 24, 30.

Upon redetermination, the DME MAC issued two separate unfavorable decisions for Appellant. Id at 23, 29. The decision for the tape explained that "[a] detailed written order (DWO) and medical records were not provided for review." Id at 24. The decision for the sensors and transmitter explained that "Policy Article A52464 states 'CGM devices covered by Medicare under the DME benefit are defined in CMS Ruling 1682R as therapeutic CGM. CGM devices that do not meet the definition of a therapeutic CGM as defined by in CMS Ruling 1682R will be denied as non-covered (no benefit).'" Id at 30. The DME MAC found the Supplier liable for the tape and the beneficiary liable for the sensors and transmitter. See id at 25, 30.

Appellant submitted a request for reconsideration. Id at 11–20. Upon reconsideration, the DME Qualified Independent Contractor (QIC), C2C Innovative Solutions, Inc., issued an unfavorable decision for Appellant. Id at 1. The DME QIC explained that "an order for the item was not submitted for review. Without an order the DME QIC cannot determine if the quantity billed is medically necessary, therefore, no payment can be allowed." Id at 4. The DME QIC found Supplier liable for payment. Id.

Appellant requested a hearing before an ALJ. Exh 3 at 1–3. With his request, Appellant's appointed representative submitted a letter detailing the beneficiary's condition and experience with the CGM. See id at 3. The ALJ held a telephonic hearing on February 27, 2019. ALJ at 1; Hearing CD. Appellant and his appointed representative (Appellant's mother) appeared. Id. At the hearing, Appellant stated that his CGM system works correctly to make his blood sugars good so that he can stay out of the hospital. See Hearing CD, beginning at 13:18:51. Appellant stated that the use of his CMG and items at issue help him control his blood sugars better now than at any other time in his life. See id.

The ALJ issued a decision that was fully favorable to Appellant. ALJ at 1. The ALJ did not cite or acknowledge CMS-1682-R. See id at 2–3. The ALJ's analysis stated:

> The QIC denied coverage on the basis that the record did not contain an order for the items at issue.
>
> In this case, the record contains a physician signed and dated order for the items at issue. Moreover, the physician notes establish that the appellant is diagnosed with diabetes and chronic kidney disease, for which he underwent a kidney transplant. In an effort to protect his kidney, the appellant is using a pump with a continuous glucose sensor, for which Medicare allowed coverage, and the items at issue work with his pump. As such, payment may be made for the supplies at issue, as billed, under §1862(a)(1)(A) of the Social Security Act.

Id at 3.

Applicable Law, Regulation, and Medicare Policy:

I. ALJ Review

A party who is dissatisfied with a QIC's reconsideration decision may seek an ALJ's review of that decision if a sufficient amount is in controversy and the party makes the request timely. 42 CFR §§ 405.1000(a), 405.1002. Generally, "[t]he issues before the ALJ . . . include all the issues for the claims or appealed matter specified in the request for hearing that were brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor." 42 CFR § 405.1032(a). An ALJ conducts a de novo review and enters a decision based upon the evidence in the record. 42 CFR § 405.1000(d). Additionally, an ALJ's "decision must be based on evidence offered at the hearing or otherwise admitted into the record, and shall include independent findings and conclusions." 42 CFR § 405.1046(a)(1). The decision must include "[t]he specific reasons for the determination, including, to the extent appropriate, a summary of any clinical or scientific evidence used in making the determination." 42 CFR § 405.1046(a)(2)(i).

All laws and regulations pertaining to the Medicare and Medicaid programs, including, but not limited to Titles XI, XVIII, and XIX of the Social Security Act (the Act) and applicable implementing regulations, are binding on ALJs. 42 CFR § 405.1063(a). Also, an ALJ is bound by NCDs and rulings by CMS. 42 CFR §§ 405.1060(a)(4), 405.1063(b). "ALJs . . . are not bound by LCDs, LMRPs, or CMS program guidance, such as program memoranda and manual instructions, but will give substantial deference to these policies if they are applicable to a particular case." 42 CFR § 405.1062(a). Further, an ALJ must explain the reasons for departing from these types of program guidance in a particular case. 42 CFR § 405.1062(b).

II. Medicare Coverage of DME

A. Statutes and Regulations

Medicare is a defined benefit program. For any item or service to be covered by Medicare, it must fall into a defined Medicare benefit category, must not be statutorily excluded, must be reasonable and necessary under § 1862(a)(1)(A) of the Act, and must satisfy other Medicare program requirements for payment.

Section 1861(n) of the Act lists certain items that are classified as DME. That list includes "blood-testing strips and blood glucose monitors for individuals with diabetes" but does not specifically mention CGMs. However, section 1861(n) is not an exhaustive list of all items that qualify as DME.

Section 1861(s)(6) lists DME among the categories of services covered under Part B. Medicare regulations define DME as equipment, furnished by a supplier or home health agency that:

(1) Can withstand repeated use.

(2) Effective with respect to items classified as DME after January 1, 2012, has an expected life of at least 3 years.

(3) Is primarily and customarily used to serve a medical purpose.

(4) Generally is not useful to an individual in the absence of an illness or injury.

(5) Is appropriate for use in the home.

42 CFR § 414.202.

B. NCD and CMS Ruling

NCD § 40.2, which was in effect on the date of service, does not address CGMs. Rather, it addresses different types of blood glucose monitors "that read color changes produced on specially treated reagent strips by glucose concentrations in the patient's blood." Id. Nevertheless, the NCD affirms that Medicare coverage of blood glucose monitoring devices "varies, with respect to both the type of device and the medical condition of the patient for whom the device is prescribed." Id. The NCD states that, generally, Medicare coverage requires that the beneficiary have a diagnosis of diabetes, the beneficiary is capable of being trained to appropriately use the device as stated by the beneficiary's physician, and the device is designed for home use. Id.

By contrast, CMS Ruling 1682-R addresses CGMs and became effective on January 12, 2017. Ruling 1682-R explains:

> The FDA recently approved expanding the indications of one CGM product to include replacement of blood glucose monitors for diabetes treatment decisions. This Ruling addresses whether "therapeutic" CGMs, which provide information that can be used to make diabetes treatment decisions meet the definition of DME. For the purpose of this Ruling, all CGMs that are approved by the FDA for use as adjunctive devices to complement, not replace, information obtained from blood glucose monitors in making diabetes treatment decisions are referred to as "non-therapeutic" CGMs.

Id at *7. The Ruling specifies that according to the FDA approval letter for the therapeutic CGM, "the therapeutic CGM is designed and approved to replace a blood glucose monitor currently classified as DME under Medicare program" and, thus, "would primarily and customarily be used to serve a medical purpose under the Medicare DME definition." Id at *8. "Medicare does not cover CGMs approved by the FDA for use as adjunctive devices to complement, not replace, information obtained from blood glucose monitors." Id at *6–7.

The Ruling concludes that a therapeutic CGM, which "is designed and approved to replace a blood glucose monitor currently classified as a DME under the Medicare program," would satisfy the criteria to be considered DME. Id at *8–11. The Ruling also specifies that the glucose sensor component and the transmitter are not durable because they would not meet the 3-year minimum lifetime requirement (MLR). Id at *9. According to the Ruling, only the receiver can be considered durable. Id at *9–10. The Ruling specifies:

> . . . the therapeutic CGM is [DME] under section 1861(n) of the Act, and therefore, falls within the scope of Medicare Part B benefit category for DME. We are not addressing any other coverage criteria through this Ruling. In the future, CMS may issue a separate policy such as a[n NCD]. In the alternative,

> MACs may issue [LCDs] concerning section 1862(a)(1)(A) of the Act, or coverage may be determined on a claim-by-claim basis.

Id at *11. In addition to payment for therapeutic CGMs, the Ruling addresses payment for accessories essential for the effective use of therapeutic CGMs, including replacement of sensors, stating: "Medicare also pays for replacement of essential accessories . . . ." Id at *13.

In conclusion, the Ruling provides:

> For CGM products that are used in the home and approved by the FDA for use in place of a blood glucose monitor for making diabetes treatment decisions, these therapeutic CGMs are primarily and customarily used to serve a medical purpose because they are used by Medicare beneficiaries with diabetes who must measure their glucose level frequently and check trends in their glucose measurements for the purpose of adjusting their diet and insulin in the treatment of their diabetes. Because they are used directly in making diabetes treatment decisions, as opposed to alerting the patient to use a blood glucose monitor to make those decisions, they are not precautionary in nature.
>
> . . .
>
> [CGM] systems are considered therapeutic CGMs that meet the definition of [DME] at section 1861(n) of the Act and 42 CFR 414.202 if the equipment—
>
> - Is approved by the FDA for use in place of a blood glucose monitor for making diabetes treatment decisions (for example, changes in diet and insulin dosage);
> - Generally is not useful to the individual in the absence of an illness or injury;
> - Is appropriate for use in the home; and
> - Includes a durable component (a component that CMS determines can withstand repeated use and has an expected lifetime of at least 3 years) that is capable of displaying the trending of the continuous glucose measurements.
>
> In all other cases in which a CGM does not replace a blood glucose monitor for making diabetes treatment decisions, a CGM is not considered DME. This Ruling does not apply to items and services furnished prior to the effective date of the Ruling.

Id at *14–15.

C. CMS and Contractor Policies

Section 1869(f)(2)(B) of the Act defines an LCD as "a determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary-or carrier-wide basis under such parts, in accordance with section 1862(a)(1)(A)." According to the *MPIM,* "[t]he LCDs specify under what clinical

circumstances an item or service is considered to be reasonable and necessary." Ch 13 § 13.1.3.[3] However, CMS has instructed contractors to communicate information not pertaining to whether the service was reasonable and necessary (for example, benefit category, statutory exclusion, and coding provisions) in policy articles. Id.

The MAC published LCD L33822[4] with respect to blood glucose monitors. L33822 stated the following with respect to CGMs:

> CGM devices covered by Medicare under the DME benefit are defined in CMS Ruling 1682R as therapeutic CGMs. Refer to the Non-Medical Necessity Coverage and Payment Rules in the LCD-related Policy Article for additional information.
> Therapeutic CGMs and related supplies are covered by Medicare when all of the following coverage criteria (1-6) are met:
>
> 1. The beneficiary has diabetes mellitus (Reference ICD-10 Codes that Support Medical Necessity section for applicable diagnoses); and,
> 2. The beneficiary has been using a BGM and performing frequent (four or more times a day) testing; and,
> 3. The beneficiary is insulin-treated with multiple (three or more) daily injections of insulin or a Medicare-covered continuous subcutaneous insulin infusion (CSII) pump; and,
> 4. The beneficiary's insulin treatment regimen requires frequent adjustment by the beneficiary on the basis of BGM or CGM testing results; and,
> 5. Within six (6) months prior to ordering the CGM, the treating practitioner has an in-person visit with the beneficiary to evaluate their diabetes control and determined that criteria (1-4) above are met; and,
> 6. Every six (6) months following the initial prescription of the CGM, the treating practitioner has an in-person visit with the beneficiary to assess adherence to their CGM regimen and diabetes treatment plan.
>
> When a therapeutic CGM (code K0554) is covered, the related supply allowance (code K0553) is also covered.
>
> If any of coverage criteria (1-6) are not met, the CGM and related supply allowance will be denied as not reasonable and necessary.

Policy Article A52464 stated:

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[3] CMS recently revised Chapter 13 of the *MPIM*. The version explained in this section is the version of the *MPIM* that was in effect on the date of service at issue in this referral. See CMS, Transmittal 473, available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R473PI.pdf (effective January 15, 2013) (visited April 22, 2019).

[4] LCDs are available online at https://www.cms.gov/medicare-coverage-database/ (visited April 22, 2019).

> CGM devices covered by Medicare under the DME benefit are defined in CMS Ruling 1682R as therapeutic CGM. *CGM devices that do not meet the definition of a therapeutic CGM as defined in CMS Ruling 1682R will be denied as non-covered (no benefit).*
>
> The supply allowance for supplies used with a therapeutic CGM system encompasses all items necessary for the use of the device and includes, but is not limited to: CGM sensor, CGM transmitter, home BGM and related BGM supplies (test strips, lancets, lancing device, calibration solutions) and batteries. Supplies or accessories billed separately will be denied as unbundling.
>
> There is no Medicare benefit for supplies used with equipment that is not classified as DME. *Coverage of CGM system supplies is limited to those therapeutic CGM systems where the beneficiary ONLY uses a receiver classified as DME to display glucose data.* If a beneficiary uses a non-DME device (smart phone, tablet, etc.) as the display device, either separately or in combination with a receiver classified as DME, the supplies shall be denied as non-covered by Medicare.
>
> . . .
>
> Codes A9276 (SENSOR; INVASIVE (E.G., SUBCUTANEOUS), DISPOSABLE, FOR USE WITH INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM, ONE UNIT = 1 DAY SUPPLY) and A9277 (TRANSMITTER; EXTERNAL, FOR USE WITH INTERSTITIAL CONTINUOUS GLUCOSE MONITORING SYSTEM) describe the supplies used with a non-therapeutic CGM.

(emphases added).

Discussion:

The ALJ erred as a matter of law by failing to address the issue of Medicare non-coverage of the items at issue, which was an issue that the DME MAC addressed in its initial and reconsideration determinations. See 42 CFR § 405.1032(a). The ALJ further erred by not applying the CMS ruling and Medicare regulatory provisions regarding DME coverage. See 42 CFR § 405.1063. We do not question the usefulness and benefit that Appellant received from using the CGM system or the items at issue in this appeal. However, Medicare coverage requirements, including whether the items used with Appellant's CGM system were statutorily allowed under a benefit category, must be met even if the items at issue were beneficial to Appellant.

Regulations and CMS rulings are binding authority for an ALJ. 42 CFR § 405.1063. Medicare sets forth the requirements for an item to be considered DME for the purposes of Part B Medicare payment. See 42 CFR § 414.202. CMS Ruling 1682-R (the Ruling), effective January 12, 2017, explained that a CGM system may be eligible for Medicare coverage under the DME benefit when the system qualifies as a *therapeutic* CGM that meets the definition of a DME. See

Ruling CMS-1682-R at *6–8. The Ruling defined a therapeutic CGM system as one that was "designed and approved to replace a blood glucose monitor currently classified as DME under the Medicare program" and emphasized that the FDA must have approved the CGM "for use in place of a blood glucose monitor for making diabetes treatment decisions." Id at *8, *13. Specifically, "Medicare does not cover CGMs approved by the FDA for use as adjunctive devices to complement, not replace, information obtained from blood glucose monitors." Id at *6–7. Although the Ruling noted that the glucose sensors in a CGM system are not durable, it allows payment for "replacement of essential accessories" used with *therapeutic* CGMs, including sensors and transmitters. Id at *13.

The ALJ did not address the issue, brought forth by the DME MAC, of whether the items at issue qualified as a Medicare benefit. See ALJ at 3; Exh 1 at 30, 39, 40, 41, 42. Generally, "[t]he issues before the ALJ . . . include all the issues for the claims or appealed matter . . . that were brought out in the initial determination, redetermination, or reconsideration that were not decided entirely in a party's favor." 42 CFR § 405.1032(a). Specifically, the MAC's redetermination for the sensor and transmitter at issue denied the items, explaining, "CGM devices covered by Medicare under the DME benefit are defined in CMS Ruling 1682R as therapeutic CGM. CGM devices that do not meet the definition of a therapeutic CGM as defined in CMS Ruling 1682R will be denied as non-covered (no benefit)." Exh 1 at 30. However, the ALJ did not address this issue.

Furthermore, the ALJ's analysis did not consider the distinction made in the Ruling between "therapeutic" CGMs that fit the definition of DME and are covered under the DME benefit, and "non-therapeutic" CGMs, which are not covered by Medicare. CMS Ruling 1682-R at *6–8, *11, *15. Particularly, the ALJ does not consider whether Appellant's CGM was "*approved by the FDA for use in place* of a blood glucose monitor for making diabetes treatment decisions" instead of being "*approved by the FDA for use as adjunctive devices to complement, not replace*, information obtained from blood glucose monitors . . . ." Id at *6–7, *15 (emphases added). The Ruling indicated that, as of its effective date, only one CGM system had been approved by FDA as "replacement of blood glucose monitors for diabetes treatment decisions" and, thus, was a therapeutic CGM covered under the DME benefit.[5] Id at *7.

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[5] According to the FDA, Dexcom G5 CGM is

> . . . designed to replace fingerstick blood glucose testing for diabetes treatment decisions. Interpretation of the Dexcom G5 results should be based on the glucose trends and several sequential readings over time. The Dexcom G5 also aids in the detection of episodes of hyperglycemia and hypoglycemia, facilitating both acute and long-term therapy adjustments.

FDA, *Dexcom G5 Mobile Continuous Glucose Monitoring System – P120005/S041*, available online at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P120005S041 (visited April 22, 2019). See also Approval Letter, online at http://www.accessdata.fda.gov/cdrh_docs/pdf12/P120005S041a.pdf (visited April 1, 2019); FDA, Summary of Safety and Effectiveness (SSED), online at http://www.accessdata.fda.gov/cdrh_docs/pdf12/P120005S041b.pdf (visited April 22, 2019).

The sensors at issue in this referral are used with the MiniMed 670G System, which the FDA states: "It is indicated for use as an adjunctive device to complement, not replace, information obtained from standard blood glucose monitoring devices." FDA, SSED for MiniMed 670G System, available at https://www.accessdata.fda.gov/cdrh_docs/pdf16/P160017b.pdf (visited April 22, 2019). Also, "The Guardian

Moreover, the ALJ's analysis did not evaluate whether the FDA had approved the CGM system at issue "to replace a blood glucose monitor," qualifying it as therapeutic under the Ruling, and did not analyze whether the item at issue met the definition of a DME. See ALJ at 3. Rather, the ALJ only addressed the issue of whether the record contained a physician signed and dated order. See id. This error is material to the outcome of Appellant's claim because it led to an order for Medicare to cover under the DME benefit accessories used with an item that did not satisfy the definition of DME.

Conclusion:

Based on the foregoing, we believe the ALJ's decision contains an error of law material to the outcome of this claim. Therefore, we refer the ALJ's decision to the Council and request own motion review.

Sensor (3) glucose values are not intended to be used directly for making therapy adjustments, but rather to provide an indication of when a finger stick may be required." Id. Also, "the G70G continuous glucose monitor does not replace a blood glucose meter." Id.